DETAILED ACTION

Claims 1-14, 17 have been canceled.

Claims ~~1-17~~ and new 15, 16 + claims 18-35 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

2. Claims 15-16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Rejections/Objections Maintained

3. Claim 17 objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim must not depend from another multiple dependent claim, and depend from a prior claim in the alternative and not depend from multiple claims simultaneously. See MPEP § 608.01(n). Accordingly, the claim 17 will not been further treated on the merits.

Rejections Withdrawn

4. Claims 1-4,10-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of the cancellation of claims 1-4, 1-14, and Applicant's discussion of the meaning of the claim limitations set forth in claims 15-16.

5. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al (1998), in light claim 1 having been canceled, and the claims are directed to the analysis of samples for gonadotropins, and not any analyte the exists in different forms.

6. Claims 1-4, and 13-14 rejected under 35 U.S.C. 102(b) as being anticipated by Rafferty, B et al (Journal of Endocrinology, 1995), in light of the fact that Rafferty et al analyze pooled samples, rather than a sample from an individual human female.

7. Claims 1-4, 13 and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Chappel (US Pat. 5,262,518), in light of the claims having been canceled.

8. Claims 1-3, 13 rejected under 35 U.S.C. 102(b) as being anticipated by Evans, LW et al (May 1997), in light of the claims having been amended to recite the term "gonadotropin" and the analyte of Evans et al is not a gonadotropin molecule.

9. Claims 10, 12, 13 rejected under 35 U.S.C. 102(b) as being anticipated by May et al (WO88/08534), in light of the claims having been canceled and newly submitted claims reciting a different combination of claim limitations directed to two signal producing means for a gonadotropin.

10. Claims 10-14 rejected under 35 U.S.C. 102(e) as being anticipated by Magginetti et al (US Pat. 6,087,184), in light of the claims having been canceled and newly submitted claims reciting a different combination of claim limitations directed to two signal producing means for a gonadotropin.

11. Claims 10-11, 13 rejected under 35 U.S.C. 102(b) as being anticipated by Meyerhoff et al (US Pat. 5,830,680) in light of the claims having been canceled and newly submitted claims reciting a different combination of claim limitations directed to two signal producing means for a gonadotropin.

Response to Arguments

12. The objection to claim 17 was not traversed. The objection is maintained for reasons of record.

New Claims/New Claim Limitations/New Grounds of Rejection

Claim Objections

13. Claims 18 and 24 are objected to because of the following informalities

a. Claim 18 recites the step of "comprising the step of", but recites steps (a), (b) and (c); the word step should be --steps--.

b.Claim 24 should recite the plural of "assay" --assays-- as two different assays are repeated. Additionally, the word "is", is recited; it should be --the-- or --if the--. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

14. Claims 18-30, 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18-30 are directed to the detection of two different forms of a gonadotropin in a human sample. What the different forms of the gonadotropin that correlates with and is indicative of the existence of a menopausal condition, especially when the individual is receiving hormone replacement therapy, the hormone of which has not been specifically defined not to be FSH, LH, GnRF, hCG or TSH, is not distinctly claimed. All forms of gonadotropom are not representative of a menopausal condition. What are the different forms being detected? The invention is not distinctly claimed.

Claims 18-22, 24-27 recite three methods steps: obtaining, performing and comparing. The performing step is not claimed as to perform the assay on the sample recited in the "obtaining" step. The rejection could be obviated by amending the claim to recite in paragraph (b), "performing contemporaneous first and second assays --on said sample--.

Claims 18-22, 24-27 are directed to a method for testing for a menopausal condition, but no correlation of the test results is determined from the comparing step. The first assay measures

a gonadotropin indicator that not does not correlate with any menopausal condition, and the second assay measures a second gonadotropin indicator. If the second assay produces a similar result to the first assay, paragraph (c), the "similar" result would not be indicative of a pre-menopausal, peri-menopausal or post menopausal condition. The first assay does not distinguish between pre-menopausal and post-menopausal conditions. A second assay producing similar result to the first assay would not provide means for distinguishing what condition exists relative to the first assay, as the first assay does not distinguish between pre-menopausal or post menopausal conditions. The invention is not distinctly claimed.

Claims 23 and 28 recite the phase "and the ratio of the two results is determined as an indication of menopausal status". Which number is in the numerator and which number is in the denominator? The first assay does not correlate with any type of menopausal status, and the second assay may or may not differ from the first assay when it produces a similar result. How can any ratio be an indication of menopausal status? An about 1/1 ratio would not indicate anything. The invention is not distinctly claimed, as any ratio would not be indicative of menopausal status, especially when the first assay does not correspond to any menopausal status. Clarification is requested.

Claim 31 recites in paragraph (c)the phrase: "means for combining the signals for the first and second gonadotropin responsive signal producing means", the preamble of claim 31 being directed to "An assay device". The cited phrase sets forth a combination of claim limitations that does not require the presence of the signal producing means from (a) and (b) to be part of the

device. The reagents in paragraphs (a) and (b) have differing functional characteristics and are not reactive/combinable one with the other, as they are directed to different indicators of a gonadotropin. The signal producing means from (a) and (b) are not required to be present in the claimed device, in light of the claim limitations requiring a combining means, and the combining means does not comprise the signal producing means from (a) and (b). The combination of claim limitations are unclear as no structural relation between each of the device components have been set forth in the claim, and the combining means recites a future tense phrase "means for combining", which does not require the presence of the signal producing means from (a) and (b) to be present in the device. Is the composition being claimed a kit? What is claimed does not define a device with inter-related components. Clarification is requested.

Claim 32 recites the phrase "signal indicative of follicle stimulating hormone". As follicle stimulating hormone is known to comprise cross reactive epitopes with other gonadotropins, how can any first and second gonadotropin-responsive signal producing means be indicative of follicle stimulating hormone when the signal could also be indicative of other gonadotropins if the reagents are not specific ? What "provided" means results in the recited indication? What reagent or reagents are a part of the claimed device?

Claims 33 and 35 recite the phrase "produce a signal as a result of binding in a detection zone". The device of claims 31 and 32, claims from which claims 33 and 35 depend, do not comprise a detection zone. No zones are recited in any claims from which claims 33 and 35

depend; the cited phrase lacks antecedent basis in the claims. No binding components have been so claimed to define a binding component for a zone.

Claims 33 and 35 recite the phrase " of a labeled specific binding reagent with a particulate direct label". Which of the two signal producing means comprises a particulate direct label? Does the device --further comprise-- an additional reagent? What is the specificity of the specific binding reagent that has not been provided in the claimed device? Is the labeled specific binding reagent an additional third labeling means? How many signal producing means are in the assay device? Clarification is requested.

Claim 34 depends from claim 32, and recites the phrase "wherein said labeled specific binding reagent is an antibody"; this phrase lacks antecedent basis in claims 31 and 32.

Claim Rejections - 35 U.S.C. § 102

15. Claims 18, 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Niccoli et al (1996, reference of record).

(independent claim 18) Niccoli et al disclose the claimed invention directed to a method of testing for a menopausal condition in a human, the method comprising the steps of

obtaining a gonadotropin-containing sample (lutropin containing sera, see page 747, coll. 1, lines 2) from a human female individual (woman and women, patient number for individuals) (see Niccoli et al page 745, Tab. 1);

performing contemporaneous first and second assays (12 different assays were performed, 1 assay using polyclonal antibodies which would measure total gonadotropin levels

(see Figure 2, page 742,legend; 11 assays that recognized at least 21 epitopes (see page 745, col. 2, middle of paragraph to end of column); additional assays used at least one anti-holomolecule (AB subunits present) monoclonal associated with an anti-beta subunit monoclonal (7/10) or an additional anti-AB subunit monoclonal (3/10); 1 kit used an anti-alpha subunit monoclonal antibody together with an anti-beta subunit monoclonal antibody (see page 746, narrative at top of page);

comparing the results of the first and second assays (see Tab. 1, page 745, bottom of page, column I or J (polyclonal, or other monoclonal assays) compared with all other assays using different combinations of monoclonal antibodies).

Instant claim 26: wherein the first and second assays are sandwich format (see page 746, which defines several sandwich formats for the first and second assays; page 747, col. 2).

Instant claim 27: different combinations of antibodies to the alpha and beta chains were used (see page 746, top of page)

16. Claims 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Matikainen et al (1992, reference of record).

(Claims 18, 19) Matikainen et al disclose the claimed invention directed to a method of testing for a menopausal condition in a human, the method comprising the steps of

obtaining a gonadotropin-containing sample (plasma from a human female individual (8 individuals were evaluated) (see pg. 820, col. 2, Subjects; page 821-page 822 : immunoradiometric assays; B-FSH and B-LH assay);

performing contemporaneous first and second assays (samples were taken every 10 minutes for 8 hours; bioactivity assay and immunoreactive assays; abstract and Figure 1, and Results section), the first assy being functional bioassay which determines biological activity independent of pre or pos t menopausal status and the second assay was an immunoassay using monoclonal antibodies (see abstract, first paragraph));

comparing the results of the first and second assays (see Figure 1, page 821, col. 2 and ratio determined from results, see page 822, Results section)

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

19. Birken et al (US Pat. 6,521,416): Birken et al disclose the claimed invention directed to a method of testing for a menopausal condition, the method comprising the steps of:

(a) obtaining a gonadotropin containing sample (urine, col. 29, line 61) from a human female individual (see col. 29, lines 4-7);

(b) performing contemporaneous first and second assays (sandwich assays: see col. 23, lines 18-41; two different forms of the gonadotropin:see col. 29, lines 45-57; the first assay was for hLH (total human LH) and the second assay was for hLH-beta-cf (fragment of LH associated with a menopausal condition);

(c) comparing the first and second assays (LH surges detected in the test were compared with levels of hLH-beta cf, see col. 29, lines 59-67 and col. 30, lines 1-17).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
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